|  | Application No.                           | Applicant(s)                  |
|--|---|-------------------------------|
| Notice of Allowability   | 10/802,440                                | NEWELL, MARTHA KAREN          |
|  | Examiner                                  | Art Unit                      |
|  | F. Pierre VanderVegt                      | 1644                          |
| · · · · · · · · · · · · · · · · · · ·  | T. Flette valluel vegt                    | 1 1044                        |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. |   |                               |
| 1. X This communication is responsive to <u>papers filed May 10, 2007</u> .  |   |                               |
| 2. The allowed claim(s) is/are 1-7 and 9-11.   |   |                               |
| <ul> <li>3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) ☐ All b) ☐ Some* c) ☐ None of the:</li> </ul>  |   |                               |
| 1. Certified copies of the priority documents have been received.  |   |                               |
| 2. Certified copies of the priority documents have been received in Application No   |   |                               |
| 3. Copies of the certified copies of the priority documents have been received in this national stage application from the   |   |                               |
| International Bureau (PCT Rule 17.2(a)).   |   |                               |
| * Certified copies not received:   |   |                               |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.   |   |                               |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.   |   |                               |
| 5. CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  |   |                               |
| (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached   |   |                               |
| 1) 🗌 hereto or 2) 🔲 to Paper No./Mail Date   |   |                               |
| (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of<br>Paper No./Mail Date  |   |                               |
| Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).  |   |                               |
| <ol> <li>DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the<br/>attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.</li> </ol>   |   |                               |
|  |   |                               |
|  |   |                               |
| Attachment(s)  |   |                               |
| 1. Notice of References Cited (PTO-892)  | 5. Notice of Informal                     | , ,                           |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948)   | 6. 🛛 Interview Summar<br>Paper No./Mail D |                               |
| 3. Information Disclosure Statements (PTO/SB/08),  | 7. 🛛 Examiner's Amend                     |                               |
| Paper No./Mail Date  4. Examiner's Comment Regarding Requirement for Deposit   | 8. Examiner's Staten                      | nent of Reasons for Allowance |
| of Biological Material   | 9.  |                               |
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# **DETAILED ACTION**

# Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on may 10, 2007 has been entered.

#### Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Helen Lockhart on July 19, 2007.

The application has been amended as follows:

# IN THE CLAIMS:

The claims have been amended in accordance with the interviews conducted on July 12, 2007 and July 19, 2007.

See attached sheets for complete replacement claim set.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/ Patent Examiner July 19,2007

> SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

1. (Currently Amended) A method for inducing apoptosis in a tumor cell, comprising:

contacting a tumor cell with an amount of a metabolic modifying agent, which when exposed to a cell causes coupling of electron transport and oxidative phosphorylation, effective to increase the mitochondrial membrane potential in the tumor cell, wherein the metabolic modifying agent is selected from the group consisting of glucose, an MHC class II HLA-DP/DQ ligand, guanosine diphosphate (GDP), sodium acetate, and a combination of phorbol myristate acetate and ionomycin, and

contacting the tumor cell with an amount of an apoptotic chemotherapeutic agent effective for inducing apoptosis in the tumor cell, wherein the apoptotic chemotherapeutic agent is selected from the group consisting of methotrexate, 5-fluorouracil, floxuridine, cytarabine, azauridine, Interferon  $\alpha$ , cisplatin, carboplatin, paclitaxelTAXOLTM, and doxorubicin ADRIAMYCINTM.

- 2. (Currently Amended) The method of claim 1, wherein the apoptotic chemotherapeutic agent is selected from the group consisting of <u>doxorubicin\_ADRIAMYCIN™</u>, cytarabine, and methotrexate.
- 3. (Previously Presented) The method of claim 1, wherein the metabolic modifying agent and the apoptotic chemotherapeutic agent are administered simultaneously.
- 4. (Previously Presented) The method of claim 1, wherein the metabolic modifying agent and the apoptotic chemotherapeutic agent are administered locally.
- 5. (Previously Presented) The method of claim 1, wherein the tumor cell is resistant to the apoptotic chemotherapeutic agent.
- 6. (Currently Amended) A method for inducing apoptosis in a tumor cell, comprising: contacting a tumor cell with an amount of a metabolic modifying agent, which when exposed to a cell causes coupling of electron transport and oxidative phosphorylation, effective to increase the mitochondrial membrane potential in the tumor cell, wherein the metabolic modifying agent is selected from the group consisting of glucose, an MHC class II HLA-DP/DQ ligand, guanosine diphosphate

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(GDP), sodium acetate, and a combination of phorbol myristate acetate and ionomycin, and staurosporine, and

contacting the tumor cell with an amount of an apoptotic chemotherapeutic agent selected from the group consisting of methotrexate, pyrimidine analogs, purine analogs, cisplatin, carboplatin, paclitaxelTAXOLTM, and tamoxifen effective for inducing apoptosis in the tumor cell, wherein the tumor cell is sensitive to the apoptotic chemotherapeutic agent, and wherein the amount of metabolic modifying agent is effective to increase mitochondrial membrane potential and the amount of apoptotic chemotherapeutic agent is effective to inhibit the proliferation of the tumor cell when the mitochondrial membrane potential is increased.

7. (Currently Amended) A method for inducing apoptosis in a tumor cell, comprising:

contacting a tumor cell with an amount of a metabolic modifying agent, which when exposed to a cell causes coupling of electron transport and oxidative phosphorylation, effective to increase the mitochondrial membrane potential in the tumor cell, wherein the metabolic modifying agent is selected from the group consisting of an MHC class II HLA-DP/DQ ligand, GDP, sodium acetate, dominant negative UCP, staurosporine and a combination of phorbol myristate acetate with ionomycin, and

contacting the tumor cell with an amount of an apoptotic chemotherapeutic agent effective for inducing apoptosis in the tumor cell, wherein the apoptotic chemotherapeutic agent is selected from the group consisting of cytarabine, and methotrexate.

# 8. (Canceled)

- 9. (Previously Presented) The method of claim 7, wherein the metabolic modifying agent and the apoptotic chemotherapeutic agent are administered simultaneously.
- 10. (Previously Presented) The method of claim 7, wherein the metabolic modifying agent and the apoptotic chemotherapeutic agent are administered locally.
- 11. (Previously Presented) The method of claim 7, wherein the tumor cell is resistant to the apoptotic chemotherapeutic agent.